# In the United States Court of Federal Claims

No. 99-949V FILED: April 5, 2002

\* \* \* \* \* \* \* \* \* \* \* \* \*

DIMITRI FLORES, by his mother and next of friend, MARIA PEREZ

Petitioner. \* Motion for Review; National

v. \* Vaccine Compensation Act, 42 \* U.S.C. §§ 300aa-1 to 300aa-34.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

\* \* \* \* \* \* \* \* \* \* \* \* \*

**DIMITRI FLORES,** by his mother and next of friend, **MARIA PEREZ,** Polk City, FL, pro se.

**LISA A. WATTS**, Torts Branch, **MARK W. ROGERS**, Acting Deputy Director, **JOHN LODGE EULER**, Acting Director, Torts Branch, Civil Division, United States Department of Justice for the defendant.

#### ORDER

## HORN, J.

The petitioner Maria Perez, acting <u>pro se</u> on behalf of her son Dimitri Flores, filed a petition under the National Vaccine Injury Compensation Act, 42 U.S.C. §§ 300aa-1 to 300aa-34 (1994) (Vaccine Act),¹ seeking compensation for injuries allegedly sustained by

<sup>&</sup>lt;sup>1</sup>Tit. XXI, § 2112, as added Nov. 14, 1986, Pub. L. No. 99-660, tit. III, § 311(a), 100 Stat. 3761; Dec. 22, 1987, Pub. L. No. 100-203, tit. IV, §§ 4303(d)(2)(A), 4307(3), 101 Stat. 1330-222, 1330-224 and amended Dec. 22, 1987, Pub. L. No. 100-203, tit. IV, §§

her son, Dimitri Flores. The November 22, 1999 petition for vaccine compensation alleged that "[a]s a result of receiving a DPT [diphtheria-pertussis-tetanus] vaccination on November 25, 1996, Dimitri Flores, (hereafter 'Dimitri') suffered a residual seizure disorder, stroke, behavioral problems, mental and physical developmental delay, and neurological sequelae ... ." The petition does not specify whether the petitioner is seeking to establish entitlement under the National Vaccine Injury Compensation Act to compensation based on presumed causation, or for an on-Table injury, 42 U.S.C. § 300aa-14, or entitlement to compensation based on actual causation, for an off-Table injury, 42 U.S.C. §§ 300aa-13(a)(1)(A), 300aa-11(c)(1). After holding a hearing, at which Ms. Perez testified, the special master issued a brief Order of Dismissal of petitioner's case on October 19, 2001. The special master concluded in the October 19, 2001 order that "the petitioner has failed to meet her evidentiary burden to establish a prima facie case."

Throughout the proceedings before the special master, the petitioner was represented by Mr. Ronald C. Homer of Boston, Massachusetts as the attorney of record. The court received the petitioner's motion for review on November 19, 2001. The motion was signed and submitted by Ms. Perez, not by Mr. Homer. The petitioner's motion initially was not filed with the clerk of this court for failure to comply with various Rules of the United States Court of Federal Claims (RCFC), including Rule 11 and 81(d), which requires all filings to be signed by the attorney of record. After inquiring as to the status of Mr. Homer as attorney for the petitioner, the court received Mr. Homer's motion to withdraw as the petitioner's attorney of record, dated November 29, 2001. A telephone status conference was held with the court, Ms. Perez, and the respondent's attorney of record. During the status conference, Ms. Perez stated she intended to proceed with her motion for review <u>pro se</u>. Following the telephone status conference, the court issued an order, dated December 5, 2001, establishing a briefing schedule and directing the clerk of court to file the petitioner's motion for review as of the date it was received by the court, November 19, 2001.

\_

<sup>4303(</sup>d)(2)(A), 4307(3), 101 Stat. 1330-222, 1330-224, Pub. L. No. 100-203, tit. IV, §§ 4307(3)(c), 4308, as amended and added July 1, 1988, Pub. L. No. 100-360, tit. IV, § 411(o)(2), (3)(A), 102 Stat. 808; Dec. 19, 1989, Pub. L. No. 101-239, tit. VI, § 6601(d)-(i), 103 Stat. 2286-2290; Nov. 3, 1990, Pub. L. No. 101-502, § 5(b), 104 Stat. 1286; Nov. 26, 1991, Pub. L. 102-168, tit. II, § 201, 105 Stat. 1102; Oct. 27, 1992, Pub. L. 102-531, tit. III, § 314, 106 Stat. 3508; Oct. 29, 1992, Pub. L. 102-572, tit. IX, §§ 902(b)(1), 911, 106 Stat. 4516; June 10, 1993, Pub. L. 103-43, tit. XX, § 2012, 107 Stat. 312; Aug. 10, 1993, Pub. L. 103-66, tit. IV, § 13632, 107 Stat. 312; Dec. 14, 1993, Pub. L. 103-183, tit. VII, § 708; Nov. 10, 1998, Pub. L. 105-362, tit. VI, § 601(a)(1)(H), 112 Stat. 3285.

<sup>&</sup>lt;sup>2</sup> The court recognizes that it owes a special responsibility to <u>pro se</u> litigants who are not members of the Bar. <u>See Haines v. Kerner</u>, 404 U.S. 519, 520-21 (1972). To that end, the court, together with defendant's counsel, have worked with Ms. Perez to try to explain the Rules of the United States Court of Federal Claims to her.

## FINDINGS OF FACT

Dimitri was born on August 11, 1992, at Our Lady of Mercy Medical Center, Bronx, New York. The petition for vaccine compensation states that Dimitri's medical records indicate no significant abnormalities at birth except an extended hospital stay of three days due to jaundice. He was ultimately released on August 14, 1992. Although the petition states that until his November 25, 1996 DPT vaccination, the one at issue in this case, "Dimitri was a healthy child ... except for usual childhood ailments," the record filed by the petitioner with the petition for vaccine compensation raises some questions in that regard. For example, a medical record from the Hunts Point Multi-Service Center, Inc., dated March 25, 1993, states, among other entries, that Dimitri "needed oxygen to breath [sic] since birth till 4 months old." A neonatal history, apparently taken during the same office visit, has boxes for frequent colds checked. In addition, in a personal history of Dimitri for his individualized education program, dated July 7, 1997, there is an entry which indicates that Dimitri experienced a traumatic birth, he got stuck in the birth canal, lacked oxygen at birth, he was born without a heartbeat, his mother suffered a seizure during delivery, and his mother had developed gestational diabetes and/or eclampsia. This record also indicates that the infant was incubated for two days. Furthermore, there are references in several places in the record that the child might have suffered a mild stoke, after the November 25, 1996 vaccinations, in addition to the alleged post-vaccination seizures.

On November 25, 1996, Dimitri Flores, at four years and three months, received his first measles-mumps-rubella vaccination, his third hepatitis B vaccination, his fourth DPT vaccination, and a *hemophilus influenzae* b vaccination. Ms. Perez, Dimitri's mother, stated in an affidavit filed with the petition for vaccine compensation, that after returning home from the November 25, 1996 vaccinations, Dimitri fell asleep. According to the affidavit, when he awoke at 6:00 p.m., he was confused and disoriented, started to shake, foam was coming out of his mouth, his tongue turned purple, and he started to get pale and cold. The petitioner called 911 and Dimitri Flores was taken to the Lincoln Medical & Mental Health Center. In her affidavit, petitioner states, based on information she says was given to her at the hospital, Dimitri had suffered either a seizure or an allergic reaction to the vaccination. According to Dimitri's mother, he had another seizure shortly after arriving at the Lincoln Medical & Mental Health Center.

During the next sixteen months, Dimitri was seen by his pediatrician, was returned to the emergency room of the Lincoln Medical & Mental Health Center, and received a number of neurology consultations. Dimitri was administered an electroencephalogram (EEG) and a magnetic resonance imaging scan (MRI). The EEG was reported normal. The petitioner states in her affidavit that the "doctor told me there were flurries on the MRI which meant that my son had suffered a minor stroke." An entry on an April 1, 1997 neurology report, however, indicates that the MRI was reported normal. Dimitri's medical records also indicate that at least two MRIs were performed during this period, but the record is not clear as to the specific dates on which they were performed. Other medical

records indicate that the first MRI administered may have shown cloudiness, perhaps indicating evidence of a stroke, but this conclusion appears to have been disapproved by a subsequent MRI.

On May 22, 2000, the petitioner filed an initial expert medical report dated May 11, 2000, authored by Dr. Marcel Kinsbourne, member of the American Board of Pediatrics and professor of psychology at New School University, New York, New York, in support of her petition. In his report, Dr. Kinsbourne states the following:

There are no contemporaneous medical records that document the abrupt onset of speech and motor deficits within three days of the DPT vaccination. But if the Court finds that Dimitri's mother's testimony is factual, then her account of the events immediately following the DPT vaccination will give me a basis for the following conclusions: In the absence of evidence for alternative causation, the abrupt onset of neurological deficits within three days of a DPT vaccination indicates an encephalopathy due to the pertussis vaccine. Dimitri's continuing psychomotor deficits, as well as subsequent seizures and need for anti-epileptic treatment, are sequelae of that acute encephalopathy. It is therefore my causation-in-fact opinion, to a reasonable degree of medical certainty, that Dimitri's residual seizure disorder and psychomotor disabilities are sequelae of a pertussis vaccine encephalopathy.

In response, and pursuant to RCFC Appendix J, Rule 4(b), the respondent filed the expert medical report of Dr. Michael A. Pollack, Chief, Neurology Division, Nemours Children's Clinic, Orlando, Florida. Based on a review of Dimitri's medical records, Dr. Pollack concluded that "[t]here is no convincing evidence of a chronic encephalopathy or other chronic neurological disorder attributable to DPT immunization."

The special master conducted a fact hearing in Orlando, Florida on April 3, 2001. Appearing as the sole witness at the hearing, the petitioner, Maria Perez, testified regarding the physical and mental conditions of her son, Dimitri Flores. The respondent did not present any evidence at the hearing. During the fact hearing, the petitioner was questioned regarding the circumstances before and after Dimitri's November 25, 1996 immunizations. Based on the testimony of Ms. Perez and the record before the court, the special master stated, "I don't find that after November 25, 1997 [sic], he [Dimitri] abruptly lost developmental skills," and that "I don't think there is a table encephalopathy here." Petitioner's counsel conceded at the hearing that the symptoms described did not support an on-Table injury under the Vaccine Act, but that the claims asserted fell into the actual causation class of cases for recovery due to vaccine related injuries, for what is known as an off-Table injury. Petitioner's counsel stated at the hearing that "[t]his is an off-table."

During the April 3, 2001 hearing, the special master concluded that, based on the facts presented, supplemental medical reports could be beneficial to the resolution of the case. The special master issued an order on August 8, 2001, directing the petitioner to

file a supplemental, expert medical report from Dr. Kinsbourne, "in light of the interpretation of Dimitri's first MRI as normal." The respondent offered further explanation of what led to the August 8, 2001 order in its response to petitioner's motion for review, "[a]fter the hearing, petitioner located Dimitri's magnetic resonance imaging ('MRI') films (which were apparently taken in December 1996) and had them reviewed and interpreted by Dr. Roy Strand, a neuroradiologist retained by petitioner, who interpreted the films as 'normal."

The petitioner filed the supplemental expert report of Dr. Kinsbourne on October 1, 2001. In the supplemental report, Dr. Kinsbourne stated the following:

In my report dated May 11, 2000, I pointed out that the medical records do not support the claim that Dimitri had suffered an encephalopathy within three days of the DPT vaccination. However, it was my opinion that if Ms. Perez' [sic] testimony were found to be factual, it would indicate an encephalopathy due to pertussis vaccine.

Recently, Dr. Roy Strand, pediatric neuroradiologist, has performed a review of the MRI films. He concluded that they did not indicate that Dimitri had suffered stroke or other encephalopathy, and that the appearances were normal. This finding is inconsistent with the neurological injuries that were implied by Ms. Perez' [sic] descriptions, summarized above. In view of this fact, it is no longer my opinion that Dimitri Flores suffered an encephalopathy due to the pertussis vaccine, or that his current disabilities are sequelae of vaccine injury.

In the October 21, 2001 brief Order of Dismissal issued by the special master,<sup>3</sup> she determined that, based on the supplemental expert medical report by Dr. Kinsbourne, which stated he was no longer of the opinion that Dimitri Flores had suffered an encephalopathy due to pertussis vaccine or that his current disabilities are sequelae of a vaccine injury, the petitioner had failed to meet her evidentiary burden to establish a prima facie case.

<sup>&</sup>lt;sup>3</sup> Although the court recognizes that the special masters have the "unenviable job of sorting through these painful cases," <u>Hodges v. Sec'y DHHS</u>, 9 F.3d 958, 961 (Fed. Cir. 1993), the court notes that the special master's order of dismissal in this case, comprised of approximately one page of double spaced text, did not make factual findings or cite one controlling legal authority except the Vaccine Act. Moreover, her citations to the exhibits were incorrectly numbered. The court, therefore, has undertaken a careful review of the record. Although this court is sympathetic to Ms. Perez and the difficulties experienced by her family, as is discussed below, the record does not support her claim on behalf of her son. The court hopes that based on this opinion, the <u>pro se</u> petitioner can more fully understand the decisions reached by the court and the special master.

## DISCUSSION

When deciding a motion to review a special master's decision, the judges of the United States Court of Federal Claims shall:

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
- (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
- (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). The legislative history of the Vaccine Act states that "[t]he conferees have provided for a limited standard for appeal from the [special] master's decision and do not intend that this procedure be used frequently, but rather in those cases in which a truly arbitrary decision has been made." H.R. Conf. Rep. No. 386, 101st Cong., 1st Sess. 512-13, 517, reprinted in 1989 U.S.C.C.A.N. 1906, 3115, 3120.

Although this court's review of decisions issued by special masters under the Vaccine Act should be conducted within the bounds described above, 42 U.S.C. § 300aa-12(e)(2), case law dictates that the judges of this court should utilize differing and distinguishable standards of review, depending upon which aspect of the case is under scrutiny. As stated by the United States Court of Appeals for the Federal Circuit:

These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed by us, as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard; and discretionary rulings under the abuse of discretion standard.

<u>Saunders v. Sec'y DHHS</u>, 25 F.3d 1031, 1033 (Fed. Cir. 1994) (quoting <u>Munn v. Sec'y DHHS</u>, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992)); <u>see also Turner v. Sec'y DHHS</u>, 268 F.3d 1334, 1337 (Fed. Cir. 2000); <u>Flanagan v. Sec'y DHHS</u>, 48 Fed. Cl. 169, 173 (2000); <u>Grice v. Sec'y DHHS</u>, 36 Fed. Cl. 114, 117 (1996); <u>Rooks v. Sec'y DHHS</u>, 35 Fed. Cl. 1, 4 (1996); <u>Cox v. Sec'y DHHS</u>, 30 Fed. Cl. 136, 142 (1993); <u>Perreira v. Sec'y DHHS</u>, 27 Fed. Cl. 29, 32 (1992), <u>aff'd</u>, 33 F.3d 1375 (Fed. Cir. 1994). The abuse of discretion standard will rarely come into play except, for example, when the special master excludes evidence. Munn v. Sec'y DHHS, 970 F.2d at 870 n.10.

The arbitrary and capricious standard of review is a narrow one. <u>Carraggio v. Sec'y DHHS</u>, 38 Fed. Cl. 211, 217 (1997); <u>Johnston v. Sec'y DHHS</u>, 22 Cl. Ct. 75, 76 (1990); <u>see</u>

Lampe v. Sec'y DHHS, 219 F.3d 1357, 1360 (Fed. Cir. 2000); Cucuras v. Sec'y DHHS, 993 F.2d 1525, 1527 (Fed. Cir. 1993); Bradley v. Sec'y DHHS, 991 F.2d 1570, 1574 (Fed. Cir. 1993); Beddingfield v. Sec'y DHHS, 50 Fed. Cl. 520, 523 (2001); Fadelalla v. United States, 45 Fed. Cl. 196, 198 (1999); Estate of Arrowood v. Sec'y DHHS, 28 Fed. Cl. 453, 457 (1993); Perreira v. Sec'y DHHS, 27 Fed. Cl. at 31-32; see also Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). The United States Court of Appeals for the Federal Circuit also has defined the arbitrary and capricious standard of review as "highly deferential." Burns v. Sec'y DHHS, 3 F.3d 415, 416 (Fed. Cir. 1993) (citing Hines v. Sec'y DHHS, 940 F.2d 1518, 1528 (Fed. Cir. 1991)). When applying the arbitrary and capricious standard, a reviewing court is not empowered to substitute its own judgment for that of a previous trier of fact. Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. at 416; see also Lonergan v. Sec'y DHHS, 27 Fed. Cl. 579, 580 (1993) (holding that this court should accord deference to a special master's decision and the reviewing court "may not substitute its own judgment for that of the special master ... .") (citing Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. at 416; Hyundai Elecs. Indus. Co. v. United States Int'l Trade Comm'n, 899 F.2d 1204, 1209 (Fed. Cir. 1990); Gamalski v. Sec'y DHHS, 21 Cl. Ct. 450, 451-52 (1990)); accord Terran v. Sec'y DHHS, 195 F.3d 1302, 1316 (Fed. Cir. 1999) reh'g denied (Fed. Cir. 2000); Fadelalla v. United States, 45 Fed. Cl. at 198-99. Instead, when determining whether a decision was arbitrary and capricious, a court "must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. at 416; see Hines v. Sec'y DHHS, 940 F.2d at 1527.

Furthermore, "[i]f the special master has considered the relevant evidence in the record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." <a href="Burns v. Sec'y DHHS">Burns v. Sec'y DHHS</a>, 3 F.3d at 416; <a href="See also Lampe v. Sec'y DHHS">Sec'y DHHS</a>, 219 F.3d at 1360; <a href="Hines v. Sec'y DHHS">Hines v. Sec'y DHHS</a>, 940 F.2d at 1528; <a href="Beddingfield v. Sec'y DHHS">Beddingfield v. Sec'y DHHS</a>, 50 Fed. Cl. at 523; <a href="Turner v. Sec'y DHHS">Turner v. Sec'y DHHS</a>, 48 Fed. Cl. 243, 246 (2000), <a href="affid">aff'd</a>, 268 F.3d 1334 (Fed. Cir. 2001); <a href="Fadelalla v. United States">Fadelalla v. United States</a>, 45 Fed. Cl. at 198-99; <a href="Lewis v. Sec'y DHHS">Lewis v. Sec'y DHHS</a>, 26 Cl. Ct. 233, 236 (1992); <a href="Murphy v. Sec'y DHHS">Murphy v. Sec'y DHHS</a>, 23 Cl. Ct. 726, 729-30 (1991), <a href="affid">aff'd</a>, 968 F.2d 1226 (Fed. Cir. 1992), <a href="cert.">cert.</a> denied, 506 U.S. 974 (1992). Thus, the decision of a special master may be found to be arbitrary and capricious only if the special master:

relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence . . . or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Hines v. Sec'y DHHS, 940 F.2d at 1527 (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983)); see also Lampe v. Sec'y DHHS, 219 F.3d at 1360.

The "not in accordance with law' standard" which applies to legal questions, warrants de novo review. Hossack v. Sec'y DHHS, 32 Fed. Cl. 769, 773 (1995) (citing Neher v. Sec'y DHHS, 984 F.2d 1195, 1198 (Fed. Cir. 1993)); see also Hanlon v. Sec'y DHHS, 191 F.3d 1344, 1348 (Fed. Cir.) reh'g denied (Fed. Cir. 1999), cert. denied 530 U.S. 1210 (2000); Bradley v. Sec'y DHHS, 991 F.2d at 1574 n.3.

The Vaccine Act provides an alternative to the traditional tort system for individuals who have suffered vaccine-related injuries. See Lowry v. Sec'y DHHS, 189 F.3d 1378, 1381 (Fed. Cir. 1999); Whitecotton v. Sec'y DHHS, 81 F.3d 1099, 1102 (Fed. Cir. 1996). The Act permits recovery of compensation for vaccine-related injuries under two distinct legal theories: (1) actual causation and (2) presumed causation under the "Vaccine Injury Table" found at 42 U.S.C. § 300aa-14(a). See Terran v. Sec'y DHHS, 195 F.3d at 1307; Whitecotton v. Sec'y DHHS, 81 F.3d at 1102. Under the actual causation theory, a petitioner makes a prima facie case of entitlement to compensation upon a showing by a preponderance of the evidence that a vaccine was the cause of the injuries (the off-Table injury). See 42 U.S.C. §§ 300aa-13(a)(1)(A), 300aa-11(c)(1). For the on-Table injury, Congress published the Vaccine Injury Table listing the various injuries associated with different vaccine types and providing associated time periods. See Terran v. Sec'y DHHS. 195 F.3d at 1307; Whitecotton v. Sec'y DHHS, 81 F.3d at 1102; 42 U.S.C. § 300aa-14. For an on-Table injury, a petitioner must show that the first "symptom or manifestation" of the injury occurred within the Table's delineated time period following the vaccination. Whitecotton v. Sec'y DHHS, 81 F.3d at 1102. Upon such a showing, causation is presumed and the petitioner is considered to have made out a prima facie case of entitlement to compensation. Id. Under both injury theories, the petitioner's establishment of a prima facie case means that the government must compensate a petitioner, unless the government can show by a preponderance of the evidence that a "factor unrelated" to the vaccine was the actual cause of the petitioner's injuries. Id.; 42 U.S.C. § 300aa-13(a)(1)(B).

Under the on-Table theory, the Vaccine Act also permits recovery if an individual suffers a significant aggravation of a pre-existing Table injury. 42 U.S.C. §§ 300aa-11(c)(1)(C)(i), 300aa-14(a); Whitecotton v. Sec'y DHHS, 81 F.3d at 1102. Congress provided for such cases

in order not to exclude serious cases of illness because of possible minor events in the person's past medical history. This provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (e.g., a child with monthly seizures who, after vaccination, has seizures on a daily basis).

<u>Id.</u> (quoting H.R. Rep. No. 99-908, at 1, <u>reprinted in 1986 U.S.C.C.A.N. 6287, 6356). A petitioner must show that the first symptom or manifestation of the significant aggravation</u>

of a Table injury occurred within the Table time period following the vaccination. 42 U.S.C. § 300aa-11(c)(1)(C)(i); Whitecotton v. Sec'y DHHS, 81 F.3d at 1103. The Vaccine Act states that "[t]he term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4). The government can rebut a prima facie case by using the "factor unrelated" test of 42 U.S.C. § 300aa-13(a)(1)(B).

In the petitioner's initial motion for review, Ms. Perez states:

Why I thought this Decision was not proper. Dimitri Flores was a normal and healthy Baby, who showed NO unnormal Abilities at the time of Birth, you can see that in his Birth Records. Dimitri Flores who also was a normal toddler and on track. He also had normal medical visits, which you can see in his medical records. He showed No unnormalities from birth till four years of age (from a healthy baby to a healthy toddler). Dimitri was full term baby which I carried for nine months. At birth he had no medical problems, which you can see in his medical records.

\* \* \*

Up to November 25, 1996 he only went to the doctor for normal check-ups and appointments for common colds. After November 25, 1996 his whole life changed. He never experienced seizures or any brain damage until after those vaccinations. The reaction to the vaccinations did not happen the same day or the day after, but it occurred within a two week period. I do know that the first MRI was clear but the second one was not.

In a supplemental filing with this court, Ms. Perez wrote:

Something did happen to my son when he took these vaccines. He is a different boy. I do not agree with the doctors' findings on this case. He did not know my son before all this happen. The doctor dismissed this case, he does not know the changes in my son.

During the fact hearing conducted in Orlando, Florida on April 3, 2001, the special master made no specific factual findings, but concluded at the hearing that the petitioner had failed to establish an on-Table injury from the DPT vaccination received on November 25, 1996. For an on-Table injury, under the Vaccine Injury Table, a petitioner must establish that the first symptom or manifestation of an injury occurred within three days of the vaccination. See 42 U.S.C. § 300aa-14. In addition, "[u]nder the statute in order to establish an on-Table injury by a preponderance of the evidence, a Petitioner must provide some type of medical evidence." Dickerson v. Sec'y DHHS, 35 Fed. Cl. 593, 599 (1996); see 42 U.S.C. § 300aa-13(a)(1) ("The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by

The Vaccine Act expressly bars the court or a special master from finding a table injury "based on the claims of the petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1). Moreover, the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight.

Cucuras v. Sec'y DHHS, 993 F.2d at 1529 (citations omitted); see also Burns v. Sec'y DHHS, 3 F.3d at 417 (holding that the special master did not err in accepting contemporaneous medical records over the conflicting testimony of fact witnesses when deciding a claim for on-Table vaccine related injuries); Grant v. Sec'y DHHS, 956 F.2d at 1148 ("Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner.") (quoting H.R. Rep. No. 908, 99<sup>th</sup> Cong., 2d Sess., pt. 1, at 15 (1986), reprinted in 1988 U.S.C.C.A.N. 6344, 6356.); Dickerson v. Sec'y DHHS, 35 Fed. Cl. at 599 (noting "the firm requirement that medical opinion evidence is still necessary in such case [sic] to support an on-Table theory.").

The medical records submitted with the petition for review do not substantiate a claim that Dimitri suffered an on-Table injury. The ambulance report dated November 25, 1996, indicates that Dimitri was alert and oriented with normal skin moisture, temperature, and color. The emergency room medical records from the same day state that Dimitri was "alert, active" and "no neurological deficit noted." Dimitri also received a medical examination on November 27, 1996, and the medical records from that physical examination indicate no neurological deficit.

Moreover, the petitioner's affidavits, the medical records submitted with the petition for vaccine compensation, and the testimony received from Dimitri's mother at the April 3, 2001 hearing in Orlando, Florida, evidence inconsistencies. Ms. Perez was questioned regarding the November 27, 1996 physical exam which reported that Dimitri did not have any neurological deficits. The petitioner denied that Dimitri was examined on November 27, 1996. In her affidavit submitted with the petition for vaccine compensation, the petitioner claimed that "Dimitri developed a rash that looked like red hives which spread throughout his body. However, the whole process was gone within thirty minutes." At the hearing, the petitioner stated that "[y]eah, the rash went away you could say like in a week." In a supplemental affidavit by petitioner submitted to the special master on May 22, 2000, Ms. Perez alleged that "within a day or two of receiving the vaccines, Dimitri suddenly lost the ability to do several things he was able to do before receiving the shots. For example, Dimitri's hands shook so badly that he could no longer write his name, or even hold a glass of milk." At the April 3, 2001 hearing, the petitioner testified that Dimitri slept most of the day following the vaccinations administered on November 25, 1996, and

on the third day following the vaccinations, he was able to pick up his utensils while eating and hold a glass.

Finally, the medical expert reports submitted by the parties do not support a claim for an on-Table vaccination injury in accordance with the requirements of the Vaccine Act. The petitioner's attorney, at the April 3, 2001 hearing in Orlando, Florida, stated that Dr. Kinsbourne's initial May 22, 2000 report did not support a claim for an on-Table encephalopathy, but that the claim was for an off-Table encephalopathy, based upon the diminished developmental skills of Dimitri after the November 25, 1996 DPT vaccination. In addition, the respondent's expert medical report submitted by Dr. Pollack states that "[t]here is no documentation that the patient [Dimitri] sustained an encephalopathy in the 72 hours following the immunization." Based on the medical reports and affidavits submitted with the petition for vaccine compensation, the testimony received at the April 3, 2001 hearing, and the expert medical reports of Drs. Kinsbourne and Pollack, this court cannot find that the special master erred in concluding that the petitioner could not establish an on-Table vaccine injury. See Cucuras v. Sec'y DHHS, 993 F.2d at 1528.

At the April 3, 2001 hearing in Orlando, Florida, the special master indicated that, although she believed that the petitioner could not establish an on-Table injury, to which petitioner's counsel agreed, she allowed for the possibility that the petitioner could establish an off-Table injury. After taking further evidence, however, the special master determined in her October 19, 2001 Order of Dismissal that the petitioner also had failed to establish a prima facie case for an off-Table injury under the Vaccine Act. The special master's Order of Dismissal found that the petitioner had failed to meet the evidentiary burden that any of the conditions allegedly suffered by Dimitri were caused by the vaccinations he received on November 25, 1996.

The United States Court of Appeals for the Federal Circuit addressed the evidentiary burden under the Vaccine Act for recovery for an off-Table or actual causation injury in <u>Shyface v. Sec'y DHHS</u>, 165 F.3d 1344 (Fed. Cir. 1999). The court held that:

establishment of <u>prima facie</u> entitlement to compensation according to the non-Table method would require the petitioner to prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury. As discussed in <u>Grant [v. Sec'y DHHS</u>, 956 F.2d 1144, 1148 (Fed. Cir. 1992)], in order to show that the vaccine was a substantial factor in bringing about the injury, the petitioner must show "a medical theory causally connecting the vaccination and the injury." There must be a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." <u>Id.</u>

<u>Id.</u> at 1352-53 (emphasis in original). Therefore, an actual causation, or off-Table injury, claim must be supported by a logical sequence of cause and effect proving the that the vaccination was the reason for the injury. <u>See Hodges v. Sec'y DHHS</u>, 9 F.3d at 961.

Moreover, "[a] reputable medical or scientific explanation must support this logical sequence of cause and effect." <u>Id.</u> (citations omitted); <u>see also Jay v. Sec'y DHHS</u>, 998 F.2d 979, 984 (Fed. Cir.) <u>reh'g denied</u> (1993); <u>Grant v. Sec'y DHHS</u>, 956 F.2d at 1148.

The petitioner states in her motion for review filed with this court that:

Dimitri was 4 years old, immediately after receiving the shots, his life changed. I was told by the doctor that Dimitri had suffered an allergic reaction to the vaccines. He had seizures due to the allergic reaction to the vaccines, and now he is unable to take any vaccines, he is at risk to contamination with all of these diseases.

The United States Court of Federal Claims addressed an off-Table, actual causation claim in <u>Wittner v. Sec'y DHHS</u>, 43 Fed. Cl. 199 (1999). In <u>Wittner</u>, the court initially observed that "[p]etitioner's burden of showing actual causation is heavy." <u>Id.</u> at 207. The petitioner in <u>Wittner</u> asserted that the special master's determination regarding causation-in-fact was arbitrary and capricious. <u>See id.</u> at 209. Analogous to this case, the petitioner in <u>Wittner</u> only cited evidence indicating a temporal link between the vaccinations and the declining health of petitioner's son. <u>See id.</u> The court in <u>Wittner</u> stated the following:

Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect. No such proof was presented in this case. Furthermore, Dr. Nigro testified that Brian's condition was not vaccine-related and his opinion was supported by the medical records and the testimony of Mrs. Wittner. Since petitioner presented no competent proof of actual causation, and since the special master reasonably relied on Dr. Nigro's opinion and the evidence supporting it, her conclusion that petitioner did not prove actual causation or significant aggravation was not arbitrary or capricious.

# Id. (citations omitted).

Not only has the petitioner not provided a reputable medical or scientific explanation that supports the petitioner's off-Table, actual causation claim, respondent's expert, Dr. Pollack, also concluded that "[c]ontemporaneous records indicate his [Dimitri's] development was delayed prior to immunization in November, 1996. There is no convincing evidence of a chronic encephalopathy or other chronic neurological disorder attributable to DPT immunization." In addition, the petitioner's own medical expert, Dr. Kinsbourne, withdrew his earlier opinion of a vaccine related injury, and in his supplemental expert report, Dr. Kinsbourne similarly stated that Dimitri's injuries were not caused by the vaccinations received on November 25, 1996.

The special master found in her Order of Dismissal of petitioner's case that because in his supplemental medical expert report, Dr. Kinsbourne, petitioner's expert, was "no

longer of the opinion that Dimitri Flores suffered an encephalopathy due to the pertussis vaccine or that his current disabilities are sequelae of a vaccine injury," the petitioner failed to meet her burden to establish a prima facie case. The court further notes that although petitioner has alleged cause and effect, she has not met the additional requirement that "[a] reputable medical or scientific explanation must support this logical sequence of cause and effect." Hodges v. Sec'y DHHS, 9 F.3d at 961(quoting Grant v. Sec'y DHHS, 956 F.2d at 1148); see also Jay v. Sec'y DHHS, 998 F.2d at 984. Therefore, after examining the medical records included in the petition for compensation, the testimony received at the hearing, and the expert medical reports, this court cannot find that the special master's finding of no on-Table or off-Table injury, and her decision to dismiss the petitioner's case, was arbitrary or capricious. The court recognizes the sad situation in which the petitioner and her son find themselves. The National Vaccine Injury Compensation Act, however, is very specific in articulating the proof required to prove entitlement to compensation under the Act. Petitioner has failed to meet the burdens of proof established by the Vaccine Act.

#### CONCLUSION

Based upon a review of the testimony, exhibits, and submissions in this case, this court finds no basis on which to overturn the special master's decision. The motion for review is denied. Each party to bear its own costs.

IT IS SO ORDERED.	
	MARIAN BLANK HORN
	Judge